DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

Vital Images, Inc
% Parthiv Shah
Sr. Regulatory Affairs Specialist
5850 Opus Parkway, Suite 300
MINNETONKA MN 55343-4414

April 17, 2015

Re: K150104
Trade/Device Name: Vitrea CT Myocardial Perfusion
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: II
Product Code: JAK, LLZ
Dated: January 19, 2015
Received: January 20, 2015

Dear Parthiv Shah,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150104

Device Name
Vitrea® CT Myocardial Perfusion

Indications for Use *(Describe)*
Vitrea® CT Myocardial Perfusion is intended to assist a trained user for the visualization of hypo/hyper dense areas in patients with angina or with a previous myocardial infarction to assess the disease state and treatment. This software provides semi-automated heart and left ventricle segmentation and color polar maps of the myocardial tissue.

The information provided is intended to be qualitative in nature and, when used by a qualified physician, may aid in the identification of myocardial enhancement defects and the follow up of such findings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part 807.92(c)

Basis for the Submission:	Modifications to a legally marketed device which are not qualified for a Special 510(k) notification
Submitter:	Vital Images, Inc. 5850 Opus Parkway Suite 300 Minnetonka, MN, 55343-4414
Establishment Registration:	2134213
Contact Person:	Parthiv Shah Sr. Regulatory Affairs Specialist Phone : 952–487–9574 Fax: 952–487–9510 E-mail: pshah@vitalimages.com
510(k) Type:	Traditional
Summary Date:	March 31, 2015
Device Trade Name:	Vitrea® CT Myocardial Perfusion Software
Device Common Name / Regulatory Description:	An accessory of Computed Tomography X-ray System
Device Classification Name:	System, X-ray, Tomography, Computed
Regulation Number:	21 C.F.R. 892.1750
Primary Product Code:	JAK
Secondary Product Code:	LLZ
Regulatory Classification:	Class II
Device Panel:	Radiology

Predicate Devices:

Predicate Device(s)	Predicate Type	Manufacturer	FDA 510(k) number
MyoPerfusion, CSMP-001A	Primary Predicate Device	Toshiba Medical Systems Corporation	K132523
CT Myocardial Analysis	Secondary Predicate Device	Vital Images, Inc.	K112531

Device Description:

Vitrea CT Myocardial Perfusion is a post-processing software option for the already cleared Vitrea software platform (K071331). It leverages the existing Vitrea platform functionalities such as Multi-Planar Reconstruction (MPR) images, Maximum Intensity Projections (MIP) and volume rendering.

Vitrea CT Myocardial Perfusion enables the visualization and analysis of perfusion defects in the myocardium. The software is intended for use with cardiac CT (Computed Tomography) studies to analyze cardiovascular anatomy and pathology and to assess the presence of hypo/hyper dense areas of myocardial tissue.

The software visualization tools provide semi-automated heart and Left Ventricle (LV) segmentation, and color overlay and polar maps of the myocardial tissue based on the Hounsfield attenuation (HU) values. The software displays the values associated with the generation of the Perfusion Index (PI) and Transmural Perfusion Ratio (TPR) maps. Perfusion Index (PI) is the ratio of the Mean Myocardial CT value to the LV blood pool CT value. Transmural Perfusion Ratio (TPR) is provided as a ratio per sector of the Endocardial CT value to the mean Epicardial CT value. The defect size scoring tool allows a user to delineate one or more contiguous 3D regions within the myocardium for independent size measurements. The user may observe the interpolated result as they are constructing the defect.

The software analysis tools include measurements and comparison ratios. The CT Myocardial Perfusion application allows users to load one or two volumes. In dual-volume cases, the volumes are displayed based on time. It also includes reporting tools for formatting findings and user selected areas of interest.

Intended Use / Indications for Use:

Vitrea® CT Myocardial Perfusion is intended to assist a trained user for the visualization of hypo/hyper dense areas in patients with angina or with a previous myocardial infarction to assess the disease state and treatment. This software provides semi-automated heart and left ventricle segmentation and color polar maps of the myocardial tissue.

The information provided is intended to be qualitative in nature and, when used by a qualified physician, may aid in the identification of myocardial enhancement defects and the follow up of such findings.

Intended for Disease / Condition / Patient Population:
The software provides Radiologists and Cardiologists with a robust dedicated suite of software tools to aid in the creation of evidence to support these physicians with their assessment of cardiac disease and functions for patients with angina or those who have had a previous myocardial infarction.

Substantial Equivalence Comparison:

- **Regulatory Comparison**

Characteristic	Vitrea CT Myocardial Perfusion software (Submission Subject)	MyoPerfusion, CSMP-001A (K132523) (Predicate Device-1)	CT Myocardial Analysis (K112531) (Predicate Device-2)	Noted Differences
		Primary Predicate Device	Secondary Predicate Device	
Classification Name	Computed tomography x-ray System	Computed tomography x-ray System	Picture Archiving and Communications System	**None** Note: The subject device has both JAK and LLZ product codes.
Regulatory Number	892.1750	892.1750	892.2050	**None** Note: The subject device has both JAK and LLZ product codes.
Product Code	Primary: JAK Secondary: LLZ	JAK	LLZ	**None**
Classification	Class II	Class II	Class II	**None**
Review Panel	Radiology	Radiology	Radiology	**None**
Decision Date	Under Review	December 12, 2013	November 18, 2011	Both predicates are cleared.

- **Intended Use Comparison with the Predicate Device-1 (Primary Predicate Device)**

Characteristic	Vitrea CT Myocardial Perfusion software (Submission Subject)	MyoPerfusion, CSMP-001A (K132523) (Predicate Device-1)	Noted Differences
Intended Use	Vitrea® CT Myocardial Perfusion is intended to assist a trained user for the visualization of hypo/hyper dense areas in patients with angina or with a previous myocardial infarction to assess the disease state and treatment. This software provides semi-automated heart and left ventricle segmentation and color polar maps of the myocardial tissue. The information provided is intended to be qualitative in nature and, when used by a qualified physician, may aid in the identification of myocardial enhancement defects and the follow up of such findings.	This software is intended to be used for the visualization of non-reversible perfusion defects (hypo/hyper dense areas) in patients with angina or with a previous myocardial infarct. Included software tools may aid a trained user in monitoring the disease state and treatment over time. This software provides maps and the values used to generate the maps. The information provided is intended to be qualitative in nature and when used by a qualified physician may aid in the identification of myocardial enhancement defects and the follow up of such findings.	**None**
Intended Users	Radiologists and Cardiologists	Radiologists and Cardiologists	**None**
Patient Population	Patients with angina or those who have had a previous myocardial infarction	Patients with angina or those who have had a previous myocardial infarction	**None**
Modality Support	CT	CT	**None**

- **Intended Use Comparison with the Predicate Device-2 (Secondary Predicate Device)**

Characteristic	Vitrea CT Myocardial Perfusion software (Submission Subject)	CT Myocardial Analysis (K112531) (Predicate Device-2)	Noted Differences
Intended Use	Vitrea® CT Myocardial Perfusion is intended to assist a trained user for the visualization of hypo/hyper dense areas in patients with angina or with a previous myocardial infarction to assess the disease state and treatment. This software provides semi-automated heart and left ventricle segmentation and color polar maps of the myocardial tissue. The information provided is intended to be qualitative in nature and, when used by a qualified physician, may aid in the identification of myocardial enhancement defects and the follow up of such findings.	Vitrea® CT Myocardial Analysis is an image analysis software application for cardiac Computer Tomography (CT) studies to visualize cardiovascular anatomy and pathology and to highlight and color code the presence of hypo/hyper dense areas of myocardial tissue.	**None** The language of Intended Use has been updated to be similar with the 510(k) cleared predicate products available in the US market.
Intended Users	Radiologists and Cardiologists	Radiologists and Cardiologists	**None**
Patient Population	Patients with angina or those who have had a previous myocardial infarction	Patients with angina or those who have had a previous myocardial infarction	**None**
Modality Support	CT	CT	**None**

- **Device Description Comparison with the Predicate Device-1 (Primary Predicate Device)**

Characteristic	Vitrea CT Myocardial Perfusion software (Submission Subject)	MyoPerfusion, CSMP-001A (K132523) (Predicate Device-1)	Noted Differences
Device Description	Vitrea CT Myocardial Perfusion is a post-processing software option for the already cleared Vitrea software platform (K071331). It leverages existing Vitrea® functionality such as Multi-Planar Reconstruction (MPR) images, Maximum Intensity Projections (MIP) and volume rendering. Vitrea CT Myocardial Perfusion enables the visualization and analysis of perfusion deficits in the myocardium. The software is intended for use with cardiac CT (Computed Tomography) studies to analyze cardiovascular anatomy and pathology and to assess the presence of hypo/hyper dense areas of myocardial tissue. The software visualization tools provide semi-automated heart and left ventricle segmentation, and color overlay and polar maps of the myocardial tissue	This device processes ECG-gated contrast enhanced cardiac scan data using MPR generated images according to the cardiac axis. The software generates polar maps, perfusion index (PI) map and Transmural Perfusion Ration (TPR) maps based upon the measured CT values of the tissue within the specified region of interest. The software displays the values associated with the generation of the Perfusion Index and TPR Maps. PI is the ratio of the Mean Myocardial CT value to the LV blood pool CT value. TPR is provided as a ratio per sector of the Endocardial CT value to the mean Epicardial CT value.	**None** Note: The added key features, except Defect Size Scoring tool, are similar to those which are available in the 510(k) cleared Predicate Device-1.

Characteristic	Vitrea CT Myocardial Perfusion software (Submission Subject)	MyoPerfusion, CSMP-001A (K132523) (Predicate Device-1)	Noted Differences
	based on the Hounsfield attenuation (HU) values. The software displays the values associated with the generation of the Perfusion Index (PI) and Transmural Perfusion Ratio (TPR) maps. PI is the ratio of the Mean Myocardial CT value to the LV blood pool CT value. TPR is provided as a ratio per sector of the Endocardial CT value to the mean Epicardial CT value. The software analysis tools include measurements and comparison ratios. The CT Myocardial Perfusion application allows to load one or two volumes. In dual-volume cases, the volumes are displayed based on time. Vitrea labels the volumes as Series1 (earlier acquisition time) and Series2 (later acquisition time). It also includes reporting tools for formatting findings and user selected areas of interest.		

- **Device Description Comparison with the Predicate Device-2 (Secondary Predicate Device)**

Characteristic	Vitrea CT Myocardial Perfusion software (Submission Subject)	CT Myocardial Analysis (K112531) (Predicate Device-2)	Noted Differences
Device Description	Vitrea CT Myocardial Perfusion is a post-processing software option for the already cleared Vitrea software platform (K071331). It leverages existing Vitrea® functionality such as Multi-Planar Reconstruction (MPR) images, Maximum Intensity Projections (MIP) and volume rendering. Vitrea CT Myocardial Perfusion enables the visualization and analysis of perfusion deficits in the myocardium. The software is intended for use with cardiac CT (Computed Tomography) studies to analyze cardiovascular anatomy and pathology and to assess the presence of hypo/hyper dense areas of myocardial tissue. The software visualization tools provide semi-automated heart and left ventricle segmentation, and color overlay and polar maps of the myocardial tissue	Vitrea® CT Myocardial Analysis is a post-processing software option for the Vitrea® software platform. It leverages existing Vitrea® functionality such as Multi Planar Reconstruction (MPR) images, Maximum Intensity Projections (MIP) and volume rendering. Vitrea® CT Myocardial Analysis enables the visualization and analysis of the myocardium. It assists in analyzing the hyper/hypo dense areas of myocardial tissue. Its visualization tools include segmentation, color coding, and polar maps. Its analysis tools include measurements and comparison ratios. It also includes reporting tools for formatting findings and user selected areas of interest.	• Two polar map plots i.e. TPR and PI are added in the already cleared Myocardial Analysis software (K112531) • Additional 3D Fusion overlay feature is provided for better viewing of cardiac vessels over colored attenuation data • Additional Defect Size Scoring tool is provided for quantifying size of individual defects within the myocardium • The software now automatically segments the Left Ventricle (LV) Blood Pool in all loaded volumes • The software allows to edit automatically generated LV Blood Pool attenuation value (LV HU) for each loaded volume <u>Note:</u> The added key features, except Defect Size Scoring tool, are similar to those which are available in the 510(k) cleared Predicate Device-1.

Characteristic	Vitrea CT Myocardial Perfusion software (Submission Subject)	CT Myocardial Analysis (K112531) (Predicate Device-2)	Noted Differences
	based on the Hounsfield attenuation (HU) values. The software displays the values associated with the generation of the Perfusion Index (PI) and Transmural Perfusion Ratio (TPR) maps. PI is the ratio of the Mean Myocardial CT value to the LV blood pool CT value. TPR is provided as a ratio per sector of the Endocardial CT value to the mean Epicardial CT value. The software analysis tools include measurements and comparison ratios. The CT Myocardial Perfusion application allows to load one or two volumes. In dual-volume cases, the volumes are displayed based on time. Vitrea labels the volumes as Series1 (earlier acquisition time) and Series2 (later acquisition time). It also includes reporting tools for formatting findings and user selected areas of interest.		

- **Similarities in Technology**

Characteristic	Vitrea CT Myocardial Perfusion software (Submission Subject)	MyoPerfusion, CSMP-001A (K132523) (Predicate Device-1)	CT Myocardial Analysis (K112531) (Predicate Device-2)	Noted Differences
		Primary Predicate Device	Secondary Predicate Device	
Software Type:				
Post-processing analysis software	✓	✓	✓	None
Input Type:				
2D or 3D CT angiography images/ data derived from DICOM 3.0 CT scans	✓	✓	✓	None
Volume:				
Support for single or dual volume exams	✓	✓	✓	None
Basic Reading Functionality:				
Conventional navigation on 2D and 3D views, change of layouts, adapt window level values for CT angiography images	✓	✓	✓	None
Segmentation and Contour Editing:				
Segment heart structures	✓	✓	✓	None
Edit and correct segmented regions	✓	✓	✓	None
Semi-Automatic segmentation of myocardium	✓	✓	✓	None
Support for single or dual volume exams	✓	✓	✓	None

Characteristic	Vitrea CT Myocardial Perfusion software (Submission Subject)	MyoPerfusion, CSMP-001A (K132523) (Predicate Device-1)	CT Myocardial Analysis (K112531) (Predicate Device-2)	Noted Differences
		Primary Predicate Device	Secondary Predicate Device	
View:				
Cardiac views: Multi-Planar Reconstruction (MPR) planes to short/long axis, Maximum Intensity Projection (MIP) formats	✓	✓	✓	None
Ability to view cardiac vessels over colored attenuation data	✓	✓	✓	None
Functional Parameters:				
Provides automatic quantified values (HU values) of perfusion results for:				
Comparison Ratios	✓	✓	✓	None
Myocardial Mass	✓	✓	✓	None
Myocardial Volume	✓	✓	✓	None
Hypo-attenuated Volume	✓	✓	✓	None
Color Overlay: Color codes the myocardial tissue to show hypo/hyper dense areas in the myocardial tissue of the heart onto MPR and 3D images	✓	✓	✓	None
Polar Maps: 17-segment or detailed bulls-eye plots for display of myocardial parameters	✓	✓	✓	None
Reporting Tools: Functionality for editing values of clinical findings such as location, characteristics, pathology, user	✓	✓	✓	None

Characteristic	Vitrea CT Myocardial Perfusion software (Submission Subject)	MyoPerfusion, CSMP-001A (K132523) (Predicate Device-1)	CT Myocardial Analysis (K112531) (Predicate Device-2)	Noted Differences
		Primary Predicate Device	Secondary Predicate Device	
assigned classifications to simplify report population, and report Templates for summarization of findings etc...				
Ability to take Snapshots	✓	✓	✓	None
Ability to export image to a PACS device	✓	✓	✓	None
Ability to save images to local computer	✓	✓	✓	None

- **Differences**

Characteristic	Vitrea CT Myocardial Perfusion software (Submission Subject)	MyoPerfusion, CSMP-001A (K132523) (Predicate Device-1)	CT Myocardial Analysis (K112531) (Predicate Device-2)	Noted Differences
		Primary Predicate Device	Secondary Predicate Device	
Perfusion Index (PI) map	✓	✓	×	The added key features, except Defect Size Scoring tool, are similar to those which are available in the 510(k) cleared Predicate Device-1.
Transmural Perfusion Ratio (TPR) map	✓	✓	×	
LV Blood Pool to Region	✓	✓	×	
LV HU	✓	✓	×	
3D Fusion view	✓	✓	×	
Defect Size Scoring tool	✓	×	×	

Summary of Non-Clinical Tests:
The changes to the Vitrea CT Myocardial Analysis (i.e. Vitrea CT Myocardial Perfusion) software were designed, developed, and tested according to written procedures that included risk management. Software testing was completed to ensure the new features operate according to defined requirements.

The following design control measures were applied to the development of the Vitrea CT Myocardial Perfusion software:

- Risk Management
- Requirements Reviews
- Code Designs
- Code Development Testing
- Code Reviews
- Design Reviews
- Verification of the software – that included performance and safety testing
- Validation of the software – that included phantom testing and simulated usability testing by experienced professionals.

Risk Management:
Each risk pertaining to these features have been individually assessed to determine if the benefits outweigh the risk. Every risk has been reduced as low as possible and has been evaluated to have a probability of occurrence of harm of "Improbable." All risks for this feature were collectively reviewed to determine if the benefits outweigh the risk. Because of the risk control measures included in this feature, it is believed that the risk for the feature as a whole is extremely low. Taking into account all risks against the benefits of this feature, it has been assessed that the benefits do outweigh the risks for this feature.

During the design review, the following conclusions were reached:

- All risks were reduced as low as possible
- The medical benefits of the device outweigh the residual risk for each individual risk and all risks together
- The overall residual risk for the project is deemed acceptable

Verification:
The software verification team's primary goal was to assure that the software fully satisfies all expected system requirements and features. Test cases were executed against the system features and requirements. As a part of creating the test cases, the verification team reviewed and monitored the Requirements Traceability Matrix ("RTM") to ensure coverage of the items within the RTM.

Validation:
The software validation team's primary goal was assuring the software conforms to user needs and intended use. The validation team conducted workflow testing that provided evidence that the system requirements and features were implemented, reviewed and met.

Internal Validation (Phantom Testing):
The software validation team provided internal validation of Vitrea CT Myocardial Perfusion software. Internal validation included internal user acceptance testing using various phantoms. Results of numerical quantities calculated by CT Myocardial Perfusion were verified using CT semi-synthetic phantoms and patient based CT datasets.

External Validation:
During external validation of the Myocardial Perfusion software, experienced users evaluated the seven-up layout, six-up scoring layout and the classification of the Transmural Perfusion Ratio (TPR). Each user felt that the Vitrea CT Myocardial Perfusion software enables the user to assess and quantify myocardial perfusion abnormalities.

Summary of Clinical Tests:
The subject of this 510(k) notification, Vitrea CT Myocardial Perfusion software, did not require clinical studies to support safety and effectiveness of the software.

Cyber and Information Security:

- ***Confidentiality***
  The Vitrea platform (K071331) relies on built in Windows Login security to limit access to the system. The Vitrea platform can only be installed and configured by an administrator of the Windows machine.

- ***Integrity***
  The Vitrea platform complies with the DICOM standard for transfer and storage of this data and does not modify the contents of DICOM instances. New DICOM produced by Vitrea is identified as such with the appropriate manufacturer tags per the DICOM standard.

- ***Availability***
  The Vitrea platform is always available to the logged on user as long as the Windows machine itself is properly maintained.

- ***Accountability***
  The Vitrea platform includes an audit capability that enables accountability by tracking authenticated and authorized user operations along with information accessed. Vitrea audit logs are time stamped, enabling correlation with Windows system logging to track information accessed by a user.

Performance Standards:
The FDA has not established mandatory performance standards and no special controls exist for this device. General software verification and validation tests were conducted to confirm proper function of the device's features.

The Vitrea software complies with the following voluntary recognized consensus standards:

Standard No.	Standards Organization	Standard Title	Version	Date
PS 3.1- 3.20 (2011) (Recognition Number 12-238)	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set (Radiology)	3	03/16/2012
ISO 14971:2007 (Recognition Number 5-70)	AAMI / ANSI / ISO	Medical Devices - Applications of Risk Management to Medical Devices	2007	03/16/2012

Standard No.	Standards Organization	Standard Title	Version	Date
IEC 62304:2006 (Recognition Number 13-32)	AAMI / ANSI / IEC	Medical Device Software - Software Life Cycle Processes (Software / Informatics)	2006	08/20/2012

Substantial Equivalence Analysis Conclusion:

Vital Images believes that Vitrea CT Myocardial Perfusion software application has a substantially equivalent intended use, indications for use and technological characteristics as the predicate devices. Any minor differences noted have been explained and do not raise any new questions of safety or effectiveness as the predicate devices. The implemented design controls, risk management and performed testing demonstrate the Vitrea CT Myocardial Perfusion software device is as safe and effective as both predicate devices. Based on the comparison data and test data Vital Images believes, the subject device should be found substantially equivalent to the predicate devices.